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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,498	03/01/2004	Alexandros Makriyannis	UCONAP/226/US	1028
2543 ALIX YALE &	IX YALE & RISTAS LLP EXAMINER			
750 MAIN ST	REET	SAEED, K	SAEED, KAMAL A	
SUITE 1400 HARTFORD, CT 06103			ART UNIT	PAPER NUMBER
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			05/30/2007	PAPER '

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No. Applicant(s)					
Office Action Summary		10/790,498	MAKRIYANNIS ET AL.				
		Examiner	Art Unit				
		Kamal A. Saeed	1626				
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with	the correspondence ac	ddress			
A SH WHIC - Exter after - If NC - Failu Any I	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DAnsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICA 36(a). In no event, however, may a repl vill apply and will expire SIX (6) MONTH , cause the application to become ABAN	ATION.  y be timely filed  IS from the mailing date of this of IDONED (35 U.S.C. § 133).	,			
Status							
. 1)🖾	Responsive to communication(s) filed on 30 Ja	anuary 2007.					
·		action is non-final.					
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 1	11, 453 O.G. 213.				
Dispositi	ion of Claims						
4)⊠	Claim(s) <u>1-20</u> is/are pending in the application.						
•	4a) Of the above claim(s) <u>15-20</u> is/are withdrawn from consideration.						
	Claim(s) is/are allowed.						
•	Claim(s) <u>1-14</u> is/are rejected.			•			
	Claim(s) is/are objected to.						
	Claim(s) are subject to restriction and/or	r election requirement.					
Annlicati	ion Papers	·					
• —	The specification is objected to by the Examine		Aba Evaninas				
الالا	10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
	Applicant may not request that any objection to the			YED 4 404(4)			
11)	Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex			• •			
Priority ι	ınder 35 U.S.C. § 119						
	Acknowledgment is made of a claim for foreign  ☐ All b)☐ Some * c)☐ None of:	priority under 35 U.S.C. § 1	19(a)-(d) or (f).				
	1. Certified copies of the priority documents	s have been received.	•				
	2. Certified copies of the priority documents	s have been received in App	olication No				
	3. Copies of the certified copies of the prior	rity documents have been re	ceived in this National	l Stage			
	application from the International Bureau	ı (PCT Rule 17.2(a)).					
* 5	See the attached detailed Office action for a list	of the certified copies not re	ceived.				
A44	44-)	·					
Attachmen	t(s) e of References Cited (PTO-892)	4) 🔲 Interview Sun	nman/ (PTO 442)				
	e of References Cited (FTO-092)  of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/N	Mail Date				
	mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date <u>11/08/04 &amp; 01/11/2005</u> .	5)  Notice of Info	rmal Patent Application				

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#### **DETAILED ACTION**

Claims 1-20 are pending in this application. Claims 14-20 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

### Information Disclosure Statement

Applicant's Information Disclosure Statements, filed on November 08, 2004 and January 11, 2005 have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

### **Priority**

This Application is a CIP of 371 of International Application No. PCT/US02/27644, filed on August 29, 2002 which claims benefit of U.S. Provisional Application No. 60/316,515 filed on August 31, 2001.

# Response to Restriction

Applicants' election with traverse of Group I, claims 1 -14 (in part), drawn to compounds

of Formula,

response filed January 29, 2007 is acknowledged.

Applicant's arguments filed January 29, 2007 have been fully considered and found partially persuasive and the search was performed to the proposed family presented by the

Applicants. However, the scope was not extended to the whole scope as presented in claim 1. However, even though an art rejection has not been made in this application, the requirement for restriction is maintained and the search has only been extended to the propsed family of compounds. It is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The Examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted (limited) the claimed subject matter accordingly. For example, the claims encompass heteroaryl groups which are variously classified, therefore "heteroaryl" has been restricted out of the generic embodiment identified for examination. The following is an illustration of the varied classification of the heteroaryl groups: pyrazinyl is classified in class 544 and subclass 336+; pyrimidinyl is clasified in class 544 and subclass 242+; pyridinyl is classified in class 546 and subclass 268.1+; oxazolyl is classified in class 548 and subclass 215+; thiazolyl is classified in class 548 and subclass 146+; etc. . . Thus, the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Moreover, it would constitute a burden to extend the search because separate search considerations would be involved in both the U.S. Patents and in the literature. The examination process following the search could easily result in different and thus burdensome considerations.

The restriction requirement here is predicated on the premise that the various compounds involved differ in structure and element so much so as to be patentably distinct, i.e. a reference which anticipated the elected compounds claimed would not even render obvious the others.

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Again, 35 U.S.C. 121 gives the Commissioner (Director) the authority to limit the examination of an application to a single invention. Applicant has not presented evidence that the examined subject matter is patentably indistinct from the non-examined subject matter. Nor have the even argued to the contrary. Moreover, the sheer number of variables, their huge possibilities, and the almost incomprehensible number of permutations and combinations thereof result in compounds so numerous and diverse so as to be a burden just to classify, search, and examine. Accordingly, the requirement to restrict is considered proper and is maintained. The search and examination of the application is directed to the generic embodiment identified for examination only.

The claims in the elected Group have not been found allowable, therefore, the possibility of rejoinder of Groups II cannot be addressed at this time. Whether the public will be inconvenienced because they will not know whether Applicants will file a divisional application to the non-elected subject matter is not a required consideration for a restriction requirement (see 35 U.S.C. 121).

The scope of the elected subject matter and the search has been extended as follows:

Compounds of formula,

,depicted in claim 1, wherein:

A is a direct bond;

B is N;

R1 is -(CH<sub>2</sub>)<sub>n</sub>-Z.

n is 0.

Z is an aromatic ring having about 5 to about 7 ring members or an aromatic ring having about 5 to about 7 ring members substituted on at least one available ring atom by an alkyl group; and wherein the connecting point between the -(CH<sub>2</sub>)<sub>n</sub>-group and the Z group can be any available ring carbon atom; or

Z is a 6 member aromatic ring or a substituted 6 member aromatic ring; and wherein the connecting point between the -(CH<sub>2</sub>)<sub>n</sub>- group and the Z group can be any available ring carbon atom; or

Z is \_\_\_\_X

wherein X and Y each independently comprise H, halogen, N<sub>3</sub>, NCS, CN, NO<sub>2</sub>, NX<sub>1</sub>X<sub>2</sub>, OX<sub>3</sub>, OAc, O-acyl, O-aroyl, NH-acyl, NH-aroyl, CHO, CF<sub>3</sub>, COOX<sub>3</sub>, SO<sub>3</sub>H, SO<sub>2</sub>NX<sub>1</sub>X<sub>2</sub>, CONX<sub>1</sub>X<sub>2</sub>, alkoxy, alkylmercapto, alkylamino, di-

alkylamino, alkylsulfinyl, alkylsulfonyl or (when Z comprises a structure having two adjacent carbon atoms methylene dioxy.

X<sub>1</sub> and X<sub>2</sub> each independently comprise H or alkyl, or

X<sub>1</sub> and X<sub>2</sub> together comprise part of a heterocyclic ring having about 4 to about 7 ring members and optionally one additional heteroatom selected from O, N or S, or

X<sub>1</sub> and X2 together comprise part of an imide ring having about 5 to about 6 members.

 $X_3$  comprises H, alkyl, hydroxyloweralkyl or alkyl-NX<sub>1</sub>X<sub>2</sub>.  $X_4$  comprises H or alkyl.

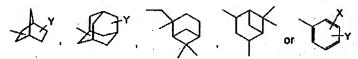
R2 is selected from a carbocyclic ring having about 4 to about 7 members, a heterocyclic ring having about 4 to about 7 members, an aromatic ring having about 5 to about 7 ring members, a heteroaromatic ring having about 5 to about 7 members, a bicyclic ring, a heterobicyclic ring, a tricyclic ring, a heterotricyclic ring, a polycyclic ring or a heteropolycyclic ring; or

R2 is 
$$-G$$

wherein G comprises CH or N, and L and J each independently comprise (CH<sub>2</sub>)<sub>n</sub>, O, NH or S. n is an integer from 0 to about 7; or

wherein G, L and J each independently comprise CH or N; or

R2 is selected from



wherein X and Y each independently comprise H, halogen, N<sub>3</sub>, NCS, Ph (phenyl), CN, NO<sub>2</sub>, NX<sub>1</sub>X<sub>2</sub>, OX<sub>3</sub>, OAc, O-acyl, O-aroyl, NH-acyl, NH-aroyl, CHO, CF<sub>3</sub>, COOX<sub>3</sub>, SO<sub>3</sub>H, SO<sub>2</sub>NX<sub>1</sub>X<sub>2</sub>, CONX<sub>1</sub>X<sub>2</sub>, alkyl, alcohol, alkoxy, alkylmercapto, alkylamino, di-alkylamino, alkylsulfinyl or alkylsulfonyl.

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X<sub>1</sub> and X<sub>2</sub> each independently comprise H or alkyl, or

X₁ and X₂ together comprise part of a heterocyclic ring having about 4 to about 7 ring members and optionally a second heteroatom selected from O, N or S, or

X<sub>1</sub> and X2 together comprise part of an imide ring having about 5 to about 6 members.

X<sub>3</sub> comprises H, alkyl, hydroxyloweralkyl or alkyl-NX<sub>1</sub>X<sub>2</sub>; or

R2 is selected from a carbocyclic ring having 6 ring atoms fused to a heterocyclic ring having from 5 to 7 ring atoms, a carbocyclic ring having 6 ring atoms fused to a heteroaromatic ring having from 5 to 7 ring atoms, a heterocyclic ring having 6 ring atoms fused to a heterocyclic ring having from 5 to 7 ring atoms, an heterocyclic ring having 6 ring atoms fused to a heteroaromatic ring having from 5 to 7 ring atoms, an aromatic ring having 6 ring atoms fused to a heterocyclic ring having from 5 to 7 ring atoms, an aromatic ring having 6 ring atoms fused to a heteroaromatic ring having from 5 to 7 ring atoms, a heteroaromatic ring having 6 ring atoms fused to a heterocyclic ring having from 5 to 7 ring atoms or a heteroaromatic ring having 6 ring atoms fused to a heteroaromatic ring having from 5 to 7 ring atoms.

R5 is H or alkyl;

R3 is CN, CH3 or CH2OH;

R4 is  $-Ph-(CH_2)_n-Z$ .

and Z represents a heterocyclic group.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-14 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. Therefore the subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-5 and 310-12 recite the term "comprises" in reference to variable such as  $\mathbb{R}^1$ ,  $\mathbb{R}^2$  or  $\mathbb{R}^3$  etc. The term "comprising" is open-ended in nature whereas a chemical compound must be claimed with precision. It is suggested to delete the term "comprises" and replace it with terms "is".

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "one of the structures 1-1, 1-2, 1-3, 1-4, 1-5.....". The structures are described in the specification. Claims must, under modern claim practice, stand alone to define an invention, and incorporation into claims by express reference to the specification is not permitted. Ex parte Fressola, 27 USPQ 2d 1608 (1993). Therefore, Applicants need to either recite all the examples contemplated in the claim or amend the claim so that it will not refer to anything in the specification.

# **Telephone Inquiry**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed, Ph.D. phone number is (571) 272-0705. The examiner can normally be reached on M-T 7:00 AM- 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signiture, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

KAMAL A. SAEED, PH.D. PRIMARY EXAMINER